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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/439,040	11/12/1999	JACOBUS J.M. VAN DONGEN	4222US	1168

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/17/2002 23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/439,040

Applicant(s)

VAN DONGEN ET AL.

Examiner

Cynthia B Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

1. Applicant's amendment filed in Paper No. 22 is acknowledged. Claims 1, 2, 4, 6, 11, 12, 17 have been amended. claims 22-29 have been added. Claims 1-12, 14-29 are pending.

All of the arguments have been thoroughly reviewed and considered. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112: Lack of adequate Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10, 16-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is drawn to a pair of nucleic acid probes and kit having comparable size, said size being selected from the group consisting of from 1 to 100 kb, from 1 to 10 kb, 7 to 15 kb, 10 to 20 kb, 10 to 30 kb, 20 to 40 kb, 30 to 50 kb, 40 to 60 kb, 50 to 70 kb, 60 to 80 kb, 70 to 90 kb and 80 to 100 kb and flanking a potential breakpoint in a single chromosome, each of said pair of probes being labeled with at least one different reporter molecule

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such that a split single arises after a break within said potential breakpoint. The claims are also drawn to a pair of nucleic acid probes of comparable size, said size being selected from the group consisting of from 1 to 100 kb, from 1 to 10 kb, 7 to 15 kb, 10 to 20 kb, 10 to 30 kb, 20 to 40 kb, 30 to 50 kb, 40 to 60 kb, 50 to 70 kb, 60 to 80 kb, 70 to 90 kb and 80 to 100 kb and flanking a potential breakpoint in a single chromosome, which pair of nucleic acid probes hybridize to a nucleic acid molecule at a genomic distance of from about 50 kb to not more than 100 kb. The claimed pair of nucleic acid probes having comparable size and flanking a potential breakpoint in a single chromosome encompass a large genus of nucleic acid sequence not adequately described or disclosed in the specification. The specification and claims focus only on the location of the probe pairs but do not describe or disclose all possible sequences that can potentially flank a potential breakpoint. Likewise the specification or claims do not describe the large genus of unknown sequences that are capable of flanking a potential breakpoint. The specification does not describe any specific pair of nucleic acid sequences that flank all possible breakpoints in a single chromosome. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species as claimed in claims 1-10, 16-21 of the specification fails to show that Applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

6. Claims 2-8, 10-12, 14-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 2-8 are indefinite at "from about" because one of skill in the art would not have been apprised of the scope of the claimed invention.

(b) Claim 10 is indefinite at "a few" because one of skill in the art would ~~not~~ have been apprised of the scope of the claimed invention.

(c) Claims 11 is confusing because the preamble recites a method for detecting a nucleic acid molecule having a chromosomal aberration but the final step recite detecting the presence of at least one different reporter molecule. Thus it cannot be clearly determined if the detecting of the different reporter signal is indicative of detecting a nucleic acid molecule having a chromosomal aberration. It is suggested amending the claim such that the preamble and method steps agree.

(d) Claim 12 is confusing because the preamble recites a method of detecting cells suspected of having a chromosomal aberration but the final step recites detecting the presence of said at least one different reporter molecule. Thus it cannot be determined if the detecting of the different reporter signal is indicative of detecting cells suspected of having a chromosomal aberration. It is suggested amending the claim such that the preamble and claim language agree.

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(e) Claims 22-29 are confusing because the preamble recites a method of detecting a break within a potential breakpoint of a single chromosome, but the final step recites determining whether a split-signal is present in said sample. Thus, it cannot be determined if the determining of a split signal is indicative of detecting a break within a potential breakpoint of a single chromosome. It is suggested amending the claim such that the preamble and claim language agree.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2, 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Croce (5,567,586, October 22, 1996). Regarding claim 2, Croce teaches a pair of nucleic acid probes of comparable size consisting of 0.1 to 10 kb, 0.5 to 5 kb, 0.8 to 3.5 kb (col. 5, lines 1-5) and flanking a potential breakpoint in a single chromosome (col. 7, lines 43-45) which nucleic acid hybridize to a nucleic acid molecule at a genomic distance greater than 3.5 kb (col. 5, lines 10-13).

Regarding claims 4 and 5, Croce et al. teach wherein the pair of probes are labeled with at least reporter molecule a fluorescent marker, such as biotin (col. 65-66).

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Regarding claims 6 and 7, Croce et al. teach wherein the pair of probes hybridizes to a single corresponding nucleic acid molecule wherein the nucleic acid molecule is at least a fragment of a chromosome (col. 7, lines 41-45).

Regarding claim 8, Croce et al. disclose wherein the chromosome is not aberrant (col. 7, lines 45-47). Therefore, the claimed invention of claims 2, 4-8 are anticipated by the reference of Croce.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.


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Cynthia B. Wilder, Ph.D.

September 9, 2002


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

9/11/02